## DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

**3223. Misbranding of Benzedrine Sulfate tablets, Seconal Sodium capsules, Sulfonamides Triplex tablets and Benadryl Hydrochloride capsules. U. S. v. Edwin L. Martin (Martin's Drug Store). Plea of nolo contendere. Defendant placed on probation for 1 year.** (F. D. C. No. 26732. Sample Nos. 45577–K to 45580–K, incl., 45969–K, 45970–K, 45973–K, 46181–K.)

INFORMATION FILED: September 26, 1949, Western District of Arkansas against Edwin L. Martin, trading as Martin's Drug Store, Hot Springs, Ark.

INTERSTATE SHIPMENT: Between the approximate dates of May 12 and December 20, 1948, from the States of Missouri, Indiana, and Pennsylvania, into the State of Arkansas.

ALLEGED VIOLATION: On or about December 28, 1948, and February 4, 5, and 12, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused a number of the tablets and capsules to be removed from the bottles in which they had been shipped, and to be repacked and sold to various persons without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the labels of the repackaged drugs bore no statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the drugs bore no directions for use.

Further misbranding, Section 502 (d), the *Seconal Sodium* was a drug for use by man and contained a chemical derivative of barbituric acid, which derivative has been by the Administrator of the Federal Security Agency, after investigation, found to be, and by regulations designated as, habit forming; and the labels of the repackaged drug failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged *Sulfonamides Triplex tablets* were fabricated from two or more ingredients, and the label of the repackaged tablets failed to bear the common or usual name of each active ingredient, namely sulfathiazole, sulfadiazine, and sulfamerazine; and, Section 502 (f) (2), the repackaged *Sulfonamides Triplex tablets* bore no labeling containing adequate warnings against use in those pathological conditions and by children where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: October 3, 1949. A plea of nolo contendere having been entered, the court placed the defendant on probation for 1 year.

**3224. Misbranding of thyroid tablets, Benzedrine Sulfate tablets, Sulfonamides Triplex tablets, diethylstilbestrol tablets, and pentobarbital sodium capsules. U. S. v. William G. Neu. Plea of guilty. Fine, $1,000.** (F. D. C. No. 29434. Sample Nos. 60942–K to 60945–K, incl., 60948–K, 60949–K.)

INFORMATION FILED: July 25, 1950, Eastern District of Missouri, against William G. Neu, a pharmacist for Neels Drugs, St. Louis, Mo.

INTERSTATE SHIPMENT: From the States of Michigan, Pennsylvania, Indiana, and New York, into the State of Missouri, of quantities of *thyroid tablets, Benzedrine Sulfate tablets, Sulfonamides Triplex tablets, diethylstilbestrol tablets,* and *pentobarbital sodium capsules.*

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*See also Nos. 3221, 3222.

NATURE OF CHARGE: While the *thyroid tablets* were being held for sale at Neels Drugs after shipment in interstate commerce, William G. Neu, on or about August 17, 1949, caused a number of these tablets to be sold and disposed of, in the original bottles in which the tablets had been shipped in interstate commerce, without requiring a prescription of a physician. When received by the defendant, the label of the tablets bore the statement "Warning—To be dispensed only by or on the prescription of a physician," and as a result, the tablets were not required to comply with Section 502 (f) (1), which requires that adequate directions for use appear in the labeling. However, by selling the tablets without a prescription, the defendant caused the exemption to expire, resulting in the misbranding of the *thyroid tablets* in violation of Section 502 (f) (1), since the bottles bore no labeling containing directions for use.

In addition to the above sale, the defendant, on or about August 15 and 17, 1949, caused various quantities of *thyroid tablets*, *Benzedrine Sulfate tablets*, *Sulfonamides Triplex tablets*, *diethylstilbestrol tablets*, and *pentobarbital sodium capsules* to be repackaged and sold without a prescription while they were being held for sale at Neels Drugs after shipment in interstate commerce, which acts resulted in the repackaged drugs being misbranded as follows: Section 502 (b) (1), the repackaged drugs, other than the *diethylstilbestrol tablets*, failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing statements of the quantity of the contents.

Further misbranding, Section 502 (d), the *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and when repackaged they failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *Benzedrine Sulfate tablets* failed to bear a label containing the common or usual name of the tablets; Section 502 (e) (2), the repackaged *Sulfonamides Triplex tablets* were fabricated from two or more ingredients, and they failed to bear a label containing the common or usual name of each active ingredient, namely, sulfamerazine, sulfadiazine, and sulfathiazole; Section 502 (f) (1), the labeling of all of the repackaged drugs, with the exception of the *Sulfonamides Triplex tablets*, failed to bear adequate directions for use; and, Section 502 (f) (2), the repackaged *Sulfonamides Triplex tablets* and the *diethylstilbestrol tablets* bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: August 18, 1950. A plea of guilty having been entered, the court imposed a fine of $1,000.

**3225. Misbranding of gelatin capsules and Newallium oleum capsules. U. S. v. 4 Cartons, etc.** (F. D. C. No. 29392. Sample No. 81191–K.)

LIBEL FILED: July 10, 1950, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about September 14, 1949, by the Curtiss Candy Co., from Chicago, Ill.

PRODUCT: 4 cartons, each containing 10,000 capsules, and 144 100-capsule boxes, 72 50-capsule boxes, and 24 25-capsule boxes, of *Newallium oleum capsules* at Philadelphia, Pa., together with a number of folders entitled "Newallium Oleum" and "New Potent Antibiotic Reported in Garlic Newallium Oleum."